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PATENT  
ATTORNEY DOCKET NO.: SHIM1110  
Gp 1/1643

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Yamada et al.  
Application No.: 09/787,181  
Filed: October 16, 2001  
IA Filing Date: September 14, 1999  
Title: SAPONIN-CONTAINING VACCINE PREPARATION

Art Unit: 1643  
Examiner: Unassigned

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Commissioner for Patents  
Washington, D.C. 20231

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TRANSMITTAL SHEET

Transmitted herewith for the above-identified application please find:

1. Information Disclosure Statement (2 pages);
2. Form PTO-1449 (2 pages);
3. Eight (8) References;
4. European Search Report (4 pages); and
5. Return postcard.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on October 17, 2002, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231

*Karen LePari*  
Karen LePari

In re Application of:  
Yamada et al.

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Page 2

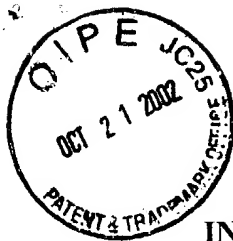
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement as the items of information contained in this statement were cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated September 10, 2002, which is not more than three months prior to the filing of this statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: October 17, 2002

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Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. 1.97, enclosed are references relating to the above-identified application. Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated September 10, 2002, which is not more than three months prior to the filing of this statement. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and copies are enclosed herewith.

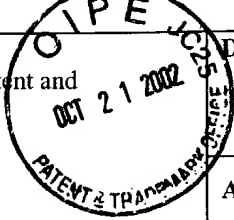
It is respectfully requested that these references be made of written record in this application.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on October 17, 2002, in an envelope addressed to:  
Commissioner for Patents, Washington, D.C. 20231

*Karen LePari*  
Karen LePari

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>SHIM 1110</b>	Serial No.: <b>09/787,181</b>
	Applicants: Yamada et al.	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Filing Date: <b>October 16, 2001</b> IA Filing Date: <b>September 14, 1999</b>	Group Art Unit: <b>1643</b>



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### U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	A1	08133948	05/28/1996	JP			YES (Abstract)
	A2	WO 96/32401	10/17/1996	PCT	A61K		NO

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

	A3	Sakuma S. et al., "Studies on the Constituents of the Root of <i>Polygala tenuifolia</i> Willdenow. I. Isolation of Saponins and the Structures of Onjisaponins G and F", <i>Chemical &amp; Pharmaceutical Bulletin</i> , Vol. 29, no. 9, 2431-2441, 1981
	A4	Sakuma S. et al., "Studies on the Constituents of the Root of <i>Polygala tenuifolia</i> Willdenow. I. On the Structures of Onjisaponins A, B and E", <i>Chemical &amp; Pharmaceutical Bulletin</i> , Vol. 30, no. 3, 810-821, 1982
	A5	Nikaido T. et al., "Inhibitors of Cyclic Adenosine Monophosphate Phosphodiesterase in <i>Polygala tenuifolia</i> ", <i>Chemical &amp; Pharmaceutical Bulletin</i> , Vol. 30, no. 6 2020-2024, 1982
	A6	Santos et al., "Haemolytic activities of plant saponins and adjuvants. Effect of <i>Periandra mediterranea</i> saponin on the humoral response to the FML antigen of <i>Leishmania donovani</i> ", <i>Vaccine Butterworth Scientific</i> , Vol. 15, no. 9 1024-1029, 1997

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449

Gray Cary\GT\6317273.1  
2102595-2

FORM PTO-1449

U.S. Department of Commerce Patent and  
Trademark Office



Docket No.

SHIM 1110

Serial No.:

09/787,181

Applicants: Yamada et al.

**SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT BY APPLICANT**

Filing Date:

October 16, 2001

IA Filing Date:

September 14, 1999

Group Art Unit:

1643

A7	Kensil et al, "Saponins as Vaccine Adjuvants", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , Vol. 13, no. 1/2 1-55, 1996
A8	Nagai et al., "Onjisaponins, from the root of <i>Polygala tenuifolia</i> Willdenow, as effective adjuvants for nasal influenza and diphtheria – pertussis – tetanus vaccines", <i>Vaccine, Butterworth Scientific</i> , Vol. 19, no. 32 4824-4834, 2001

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Form 1449

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GRÜNECKER, KINKELDEY, STOCKMAIR  
& SCHWANHÄUSSER  
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- 9. Sep. 2002  
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Datum/Date

10.09.02

Zeichen/Ref./Réf.

EP21068-031/do✓

Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°.

99943341.0-2402-JP9905019 ✓

Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire

THE KITASATO INSTITUTE✓

## COMMUNICATION

The European Patent Office herewith transmits as an enclosure the European search report for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

☒ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

## REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
① X,D✓	SAKUMA S ET AL: "CONSTITUENTS OF THE ROOT OF POLYGALA-TENUIFOLIA 1. ISOLATION OF SAPONINS AND THE STRUCTURES OF ONJISAPONIN G AND ONJISAPONIN F" CHEMICAL & PHARMACEUTICAL BULLETIN (TOKYO), vol. 29, no. 9, 1981, pages 2431-2441, XP001094024 ISSN: 0009-2363	1-6	A61K39/39 A61K35/78 C07H15/256
Y	* the whole document *	7-9	
② X,D✓	SAKUMA S ET AL: "CONSTITUENTS OF THE ROOT OF POLYGALA-TENUIFOLIA 2. STRUCTURES OF ONJISAPONIN A ONJISAPONIN B AND ONJISAPONIN E" CHEMICAL & PHARMACEUTICAL BULLETIN (TOKYO), vol. 30, no. 3, 1982, pages 810-821, XP001094023 ISSN: 0009-2363	1-6	
Y	* the whole document *	7-9	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
③ X✓	NIKAIDO T ET AL: "INHIBITORS OF CYCLIC AMP PHOSPHO DI ESTERASE IN POLYGALA-TENUIFOLIA" CHEMICAL & PHARMACEUTICAL BULLETIN (TOKYO), vol. 30, no. 6, 1982, pages 2020-2024, XP001094027 ISSN: 0009-2363	1-6	A61K C07H
④ X✓	PATENT ABSTRACTS OF JAPAN vol. 1996, no. 09, 30 September 1996 (1996-09-30) & JP 08 133948 A (SHISEIDO CO LTD), 28 May 1996 (1996-05-28) * abstract *	1-6	
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search MUNICH		Date of completion of the search 23 August 2002	Examiner Irion, A
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03 92 (P04C04)

EP 99 94 3341

23-08-2002

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 08133948	A	28-05-1996	NONE





DOCUMENTS CONSIDERED TO BE RELEVANT							
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)				
⑤ Y✓	SANTOS W R ET AL: "Haemolytic activities of plant saponins and adjuvants. Effect of <i>Periandra mediterranea</i> saponin on the humoral response to the FML antigen of <i>Leishmania donovani</i> ". VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 15, no. 9, 1 June 1997 (1997-06-01), pages 1024-1029, XP004115371 ISSN: 0264-410X * abstract * * page 1027, left-hand column, line 31 - line 39 * * page 1025, right-hand column, line 4 * ---	7-9					
⑥ A✓	KENSIL ET AL: "Saponins as vaccine adjuvants" CRITICAL REVIEWS IN THERAPEUTIC DRUG CARRIER SYSTEMS, XX, XX, vol. 13, no. 1/2, 1996, pages 1-55, XP002091371 ISSN: 0743-4863 * the whole document * ---	1-9	TECHNICAL FIELDS SEARCHED (Int.Cl.7)				
⑦ T✓	NAGAI T ET AL: "Onjisaponins, from the root of <i>Polygala tenuifolia</i> Willdenow, as effective adjuvants for nasal influenza and diphtheria-pertussis-tetanus vaccines" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 19, no. 32, 14 September 2001 (2001-09-14), pages 4824-4834, XP004303179 ISSN: 0264-410X * the whole document * -----	1-9					
The supplementary search report has been based on the last set of claims valid and available at the start of the search.							
Place of search MUNICH		Date of completion of the search 23 August 2002	Examiner Irion, A				
<table border="0"><tr><td>CATEGORY OF CITED DOCUMENTS</td><td>T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons ----- &amp;: member of the same patent family, corresponding document</td></tr><tr><td>X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document</td><td></td></tr></table>				CATEGORY OF CITED DOCUMENTS	T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons ----- &: member of the same patent family, corresponding document	X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document	
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